Public Title	pre-emptive vs. (MRD)-triggered administration of Imatinib after stem celltransplantation for Ph+/BCR-ABL+ALL
Scientific Title	A randomized, multicenter phase III-study to compare the efficacy and safety of early pre -emptive versus minimal residual disease (MRD)-triggered administration of Imatinib Mesylate (STI571, Glivec) after stem cell transplantation for Ph+/BCR-ABL+ acute lymphoblastic leukemia (Ph+ALL).
Short Title	ALL GMALL Imatinib post SZT
Id KN/ELN	LN_GMALLE_2004_62
Trialgoup	GMALL
Type of Trial	multicentric, randomized
Phase	Phase III
Disease	Acute lymphoblastic leukemia(ALL) Stem cell transplantation Acute lymphoblastic leukemia(ALL) Ph/BCR ABL +
Stage of Disease	.
Outcomes	- Molecular or hematologic relapse during therapy (Primary Outcome) - Time to conversion to MRD positivity after therapy - Overall survival after therapy - Disease free survival after therapy - Transplantant-related mortality during and after sct - Frequency of graft failure after sct - Rate and severity of acute and chronic GvHD after sct - Severe non-hematologic toxicity during therapy - Grade III/IV hematologic toxicity during therapy
Inclusion Criteria	- Male or female patients 18 years of age - Patients with a confirmed diagnosis of Philadelphia chromosome-positive ALL (Ph+ALL) or chronic myeloid leukemia (CML) in lymphoid blast crisis (LyBC) who underwent allogeneic or autologous stem cell transplantation no longer than 6 weeks prior to randomization - Hematologic recovery to platelets >50/nl and ANC> 1x109/L - Complete hematologic remission demonstrated by bone marrow cytology or histology - Negative pregnancy test in all patients of childbearing potential prior to the initiation of study drug. Barrier contraceptive precautions are to be used throughout the trial in both sexes - Voluntary written informed consent.
Exclusion Criteria	- Patients with an ECOG Performance Status Score 3 - Creatinine levels more than 2x¡¯s the ULN at the laboratory where the analysis was performed. - Total serum bilirubin more than 2 x¡¯s the upper limit of the normal range (ULN) at the laboratory where the analyses were performed. - AST (SGOT) or ALT (SGPT) more than 5x¡¯s the upper limit of the normal range (ULN) at the laboratory where the analyses were performed. - Graft versus host disease WHO grade IV - Patients with NYHA grade 3/4 cardiac disease. - Patients with an active severe infection or any serious concomitant medical condition. - Patients with psychiatric disease or a history of non-compliance to medical regimens or who are considered potentially unreliable.

Age	>= 18 years
Status	Closed
start of Recruitment	01.06.2004
Recruiting countries	Germany
Target Sample Size	80
Leader	Ottmann, Prof. Dr., Oliver Universitätsklinikum Frankfurt/Main Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern Kai 7 60590 Frankfurt / Main Tel: +49 (0)69 6301 87070 Fax: +49 (0)69 6301 4170 Email: ottmann@em.uni-frankfurt.de
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Centre of Trial	Universitätsklinikum Frankfurt
Diagnostics	**MRD-Analysis** Molekulargenetik-Labor der Med.Klinik II, Universitätsklinikum Frankfurt **STI-Level Measurement** Pharmakokinetisches Labor, Universitätsklinikum Dresden (HPLC-Labor 10D) **Cytogenetics** Tumorzytogenetik-Labor, Universität Düsseldorf
Sponsors	Universitätsklinikum Frankfurt
Supporters	Universitätsklinikum Frankfurt Theodor-Stern Kai 7 60590 Frankfurt / Main
Interventions	- Imatinib : according to protocol